UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION
PREVENTION

MEMORANDUM

Date: September 18, 2012

Subject: Efficacy Review for Wedge Disinfectant
EPA Reg. No. 88494-R
DP Barcode: D402608

From: Lorilyn M. Montford
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Ph.D., Team Lead
Efficacy Evaluation Team
Antimicrobials Division (7510P)
9/20/12

To: Jacqueline Campbell-McFarlane, PM 34/Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: North American Infection Control, Ltd.
209 Strathearn Road
Toronto, Canada M6C1S5 Canada

FORMULATION FROM LABEL:

Active Ingredient	% by wt.
Ethyl Alcohol	72.4202%
Didecyl Dimethyl Ammonium Chloride	0.3278%
Inert Ingredients	27.2022%
Total	100.0000%

I BACKGROUND

The product, Wedge Disinfectant (EPA Registration No. 88494-R) is a new product. The applicant has requested to register the product as a disinfectant (bactericide, virucide, fungicide, tuberculocidal) and non-food contact sanitizer for use on hard, non-porous surfaces in households, institutional and commercial environments, medical, dental, ambulatory, veterinary settings, hotels, motels, factories, and food processing and packaging establishments. The label claims that the product is a one-step cleaner/disinfectant indicating that it is effective in the presence of a 5% organic soil load. Studies were conducted at Gibraltar Laboratories, located at 122 Fairfield Road, Fairfield, NJ 07004-2405.

This data package included a letter from the applicant dated, May 10, 2012, twenty-three (23) studies (MRID No. 4488252-10 thru 4488252-32), Statements of No Data Confidentiality Claims, Good Laboratory Practices statement, and the proposed label.

II USE DIRECTIONS

The product is designed for sanitizing and disinfecting hard, non-porous surfaces, including bathroom surfaces, countertops, sinks, bed frames, shower stalls, tables, telephones, chairs, carts, toilet seats, tiles, traction devices, MRI, CAT scales, paddles, wheelchairs, ultrasound transducers, probes, shopping carts, grocery carts, trash cans, appliance exteriors, diaper pails, protective gear, goggles, spectacles, face shields, gas masks, and respirators. According to the label the product may be used on the following surfaces: stainless steel, metal, glazed porcelain, glazed ceramic tile, plastic surfaces. Directions on the proposed label state the following for disinfection: Thoroughly wet the surface to be treated. Treated surface must remain visibly wet for one minute to achieve complete disinfection [or kill] of all pathogens listed on this label. For visibly soiled surfaces, clean before following disinfecting instructions. For general cleaning the proposed label states the following: Wet surface sufficiently and clean with a mop, sponge, cloth, nonwoven wipe, or other suitable cleaning instrument.

II AGENCY STANDARDS FOR PROPOSED CLAIMS

<u>Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments</u>

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59

out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi)

The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 product samples representing 2 different product lots using the AOAC Fungicidal Test. The highest dilution that kills all fungal spores is the minimum effective concentration.

IV COMMENTS ON SUBMITTED EFFICACY STUDIES

1. MRID 488252-10 "AOAC 18th Edition Hospital Claim Germicidal Spray Test on NAIC 88494-1 vs. *Pseudomonas aeruginosa*, ATCC 15442, *Staphylococcus aureus*, ATCC 6538 and *Salmonella enterica*, ATCC 10708" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 10/06/2011. Laboratory Project Number: GR 2863.

This study was conducted against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538) and *Salmonella enterica* (ATCC# 10708). Three lots (Lot nos. P7980, P8073 and P8176) of the product, Wedge Disinfectant, one at least 60 days old, were tested using the AOAC Official Methods of Analysis, 18th edition (protocol attached). The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 66 (60 for test, 3 for quantitative controls and 3 for qualitative controls) sterile 1" x 1" glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours, and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

2. MRID 488252-11 "AOAC 18th Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Acinetobacter baumannii*, ATCC 19606" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2944.

This study was conducted against *Acinetobacter baumannii* (ATCC# 19606). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45°angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours, and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

3. MRID 488252-12 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Burkholderia cepacia*, ATCC 25416" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2944.

This study was conducted against *Burkholderia cepacia* (ATCC# 25416). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The

inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

4. MRID 48825213 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Campylobacter jejuni*, ATCC 29428" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 01/09/2012. Laboratory Project Number: GR 2946.

This study was conducted against *Campylobacter jejuni* (ATCC# 29428). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Fluid Thioglycollate supplemented with 0.5% polysorbate 80 and 0.07% Lecithin, and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

5. MRID 488252-14 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Escherichia coli* serotype O157:H7, ATCC 35150" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/23/2011. Laboratory Project Number: GR 2915.

This study was conducted against *Escherichia coli* serotype O157:H7 (ATCC# 35150). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation,

neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

6. MRID 488252-15 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Klebsiella pneumoniae*, ATCC 4352" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/23/2011. Laboratory Project Number: GR 2913.

This study was conducted against *Klebsiella pneumoniae* (ATCC# 4352). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

7. MRID 488252-16 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Listeria monocytogenes*, ATCC 984" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/23/2011. Laboratory Project Number: GR 2914.

This study was conducted against *Listeria monocytogenes* (ATCC# 984). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Brain Heart Infusion Broth supplemented with 0.07% Lecithin and 0.5% polysorbate 80, and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

8. MRID 488252-17 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Staphylococcus aureus* (MRSA), ATCC 33591" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/14/2011. Laboratory Project Number: GR 2910.

This study was conducted against *Staphylococcus aureus* (MRSA) (ATCC# 33591). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, antibiotic resistance confirmation, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

9. MRID 488252-18 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Streptococcus pyogenes*, ATCC 19615" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/23/2011. Laboratory Project Number: GR 2912.

This study was conducted against *Streptococcus pyogenes* (ATCC# 19615). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

10. MRID 488252-19 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Enterococcus faecium* (VRE), ATCC 51559" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 11/23/2011. Laboratory Project Number: GR 2911.

This study was conducted against *Enterococcus faecium* VRE (ATCC# 51559).

Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of each culture broth containing 5% fetal bovine serum was spread onto 25 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 40 minutes at 36±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Letheen Broth and agitated. The jars were incubated at 36±1°C for 48±2 hours and observed for turbidity. Controls included those for carrier quantitation, neutralization confirmation, sterility, purity, antibiotic resistance confirmation, and viability. Efficacy data were generated at the lower certified limits for the two active ingredients.

11. MRID 488252-20 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Mycobacterium bovis*, ATCC# 35743" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 10/17/2011. Laboratory Project Number: GR 2864.

This study was conducted against *Mycobacterium bovis* (ATCC# 35743). Two lots (Lot nos. P7980 andP8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.03 mL of each culture broth containing 5% fetal bovine serum was spread onto 24 (10 for test/lot, 2 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 30 minutes at 37±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45°angle, 6 – 8 inches until the slides were completely wet. The lids were placed on the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 10 mL of horse serum and agitated. Next, the glass slide carriers from the horse serum jars were sub-transferred into wide-mouth jars containing 200 mL of sterile MPB Broth containing 0.5% polysorbate 80 and 0.07% Lecithin. From the same jar of serum, 2 mL of the serum was added into separate wide-mouth jars containing 200 mL of sterile Dubos Broth containing 0.5% polysorbate 80 and 0.07% Lecithin. Next, the subcultures were transferred into wide mouth jars containing 200 mL of sterile 7H9 broth containing 0.5% polysorbate 80 and 0.07% Lecithin. The jars were then incubated at 37+1°C for 60 days and observed for growth [turbidity]. Controls included those for viability, sterility, carrier quantitation, neutralization effectiveness confirmation, and purity. Efficacy data were generated at the lower certified limits for the two active ingredients.

12. MRID 488252-21 "AOAC 18th Edition Supplemental Claim Efficacy Germicidal Spray Test on NAIC 88494-1 disinfectant vs. *Trichophyton mentagrophytes*, ATCC 9533" for Wedge Disinfectant, by Jozef Mastej. Study Completion Date: 09/12/2011. Laboratory Project Number: GR 2865.

This study was conducted against *Trichophyton mentagrophytes* (ATCC 9533). Two lots (Lot nos. P7980 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The product was received ready-to-use and undiluted in 6 white plastic spray bottles. A 0.01 mL of conidia spore

suspension containing 5% fetal bovine serum was spread onto 15 (10 for test/lot, 3 for quantitative controls and 2 for qualitative controls) sterile 1 x 1 inch glass slides per lot. The inoculated glass slides, each in a sterile Petri dish, were dried for 20 minutes at 37±1°C in an incubator. Post drying, the spray disinfectant product was sprayed at a 45° angle, 6 – 8 inches until the slides were completely wet. The lids were placed over the Petri dishes. After one minute, the slides were transferred into wide-mouth jars containing 20 mL of Glucose Broth containing 0.5% Polysorbate 80 and 0.07% Lecithin. The jars were incubated at 28-32°C for 12 days and observed for turbidity. Controls included those for numbers, neutralizer confirmation effectiveness, sterility, and challenge microorganism confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

13. MRID 488252-22 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Human Coronavirus, ATCC VR-1558" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2875.

This study was conducted against Human Coronavirus (ATCC VR-1558). Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Human Coronavirus stock pools were prepared from the supernatant of infected HCT-8 Cell culture. Each Human Coronavirus stock pool was tittered and stored in an ultra-low temperature freezer. HCT-8 cell culture was maintained in DMEM/2% FBS/PS during viral propagation. Frozen viral stock was thawed on the day of the test and fetal bovine serum was added to the virus used in the study. Total amount of soil was adjusted to be 5%. An aliquot of 0.2 mL of the virus, containing the 5% organic load, was spread over a marked area of a sterilized glass Petri dish. The virus was allowed to dry completely under the biosafety cabinet at room temperature. The virus dried at 22.4°C and 52.2% relative humidity. Drying time was 12 minutes and 46 seconds. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45°angle, 4" inches away from the surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. An aliquot, 0.1 mL of disinfectant/virus reaction mixture was removed and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100 FBS, followed by Sephadex column filtration. The collected eluate was designated 10^{-2} dilution. Subsequent serial dilutions were performed to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. The wells contained 10 mL of DMEM/2% FBS/PS (3-fold). Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days and recorded based viral CPE. Controls included those for cell viability, carrier counts, virus stock, plate recovery/column titer, cytotoxicity and neutralization confirmation effectiveness. Efficacy data were generated at the lower certified limits for the two active ingredients.

13. MRID 488252-23 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Human Hepatitis B Virus Using Duck Hepatitis B Virus As A Surrogate" , acquired from GBL" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 3/13/2012. Laboratory Project Number: GR 2884.

This study was conducted against Human Hepatitis B Virus Using Duck Hepatitis B Virus as surrogate. Two lots (Lot no.'s P8176, P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th ed. for testing. The Human Coronavirus stock pools were prepared from the supernatant of infected HCT-8 Cell culture. DHBV stock pools were harvested by GBL from congenitally infected animals. DHBV pools contain high organic load close to 100%. They were diluted to bring down the cell culture medium to at least 5%. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was allowed to dry completely under the biosafety cabinet at room temperature. The virus dried at 22.6°C and 31.8% relative humidity. Drying time was 11 minutes and 30 seconds. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at 45 degree angles, 4 inches away. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% FBS. The mixture was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-3} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. After inoculation, PDH was monitored for seven days and any morphological change was recorded. Presence or absence of virus survivors was determined based on immunofluorescence assay (IFA). Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity and neutralization effectiveness control. Efficacy data were generated at the lower certified limits for the two active ingredients.

14. MRID 488252-24 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Human Hepatitis C Virus Using Bovine Viral Diarrhea Virus As A Surrogate", acquired from USDA" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 3/12/2012. Laboratory Project Number: GR 2885.

This study was conducted against Human Hepatitis C Virus Using Bovine Viral Diarrhea Virus as surrogate. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Bovine Viral Diarrhea (BVDV) virus was purchased from USDA, prepared from the supernatant of infected BT cell culture. The cell culture was maintained in DMEM/10%HS/PS. The virus pool contained 10% organic load. The pool was titered and stored in an ultra-low freezer, thawed the day of the test and further diluted to 1:10. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was dried at 23°C and 22.6% relative humidity for approximately 7 minutes. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at 45° angle, 4 inches away from the surface. Post contact time, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. An aliquot of 0.1 mL disinfectant/virus reaction mixture was removed, and the disinfection activity was neutralized by diluting (30-fold) with 2.9 mL of 100% HS and filtering through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were performed to 10^{-3} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated

plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness control. Efficacy data were generated at the lower certified limits for the two active ingredients.

15. MRID 488252-25 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Herpes Simplex Virus Type 1 (HSV-1) ATCC VR-539" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/07/2011. Laboratory Project Number: GR 2872.

This study was conducted against Herpes Simplex Type 1 (HSV-1) ATCC VR-539. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Herpes Simplex Virus stock pools were prepared from the supernatant of infected Vero cell culture. The Vero cell culture was maintained in DMEM/5% FBS/PS. Thus, the harvested viral stock contains 5% organic load. The pool was titered and stored in an ultra-low freezer, thawed the day of the test and further diluted. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was dried at 23.5°C and 54.8% relative humidity for 12.3 minutes. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at 45° angles, 4 inches away from surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one(1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% HS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were performed to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

16. MRID 488252-26 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Human Immunodeficiency Virus (HIV-1)" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2868.

This study was conducted against Human Immunodeficiency Virus (HIV-1). Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Human Immunodeficiency Virus (HIV-1) stock was purchased from Advanced Biotechnologies, Inc. It was titered and cryo-stored in a liquid nitrogen biological system. The MT-2 cell culture was maintained in RPMI-I640/10%FBS/PS. The frozen viral stock was thawed on the day of testing. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was dried at 23.7°C and 52.3% relative humidity at 12.69 minutes. The host MT-2 cells were plated into 6-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done

at a 45° angle, 4 inches away from the surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one(1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% HS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

17. MRID 488252-27 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Influenza Virus Type A2" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2874.

This study was conducted against Influenza A2 Virus, Strain A/Hong Kong/8/68. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Influenza Virus Type A2 stocks were prepared from the supernatant of infected MDCK cell culture. Each Influenza stock pool was titered and stored in an ultra-low temperature freezer. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was dried at 23.2°C and 51.8% relative humidity at 13.69 minutes. The host MDCK cells were plated into 24-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45° angle, 4 inches away from hard surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one (1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of EX-Cell MDCK Serum-Free medium/L-glutamine/PS/Trypsin 2.5µg/mL and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

18. MRID 488252-28 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Norovirus Using Feline Calicivirus as Surrogate" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 03/12/2012. Laboratory Project Number: GR 2883.

This study was conducted against Norovirus Using Feline Calicivirus as approved surrogate. Two lots (Lot nos. P8176 and P8073) of the product, Wedge

Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Feline Calicivirus stocks were prepared from the supernatant of infected CRFK cell culture. Each Feline Calicivirus stock pool was titered and stored in an ultra-low temperature freezer. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus was allowed to dry completely under the biosafety cabinet at room temperature. The virus dried at 22.8°C and 39.6% relative humidity for approximately 9 minutes. The CRFK cells were plated into 24-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45°angle, 4 inches away from surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. An aliquot of the 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% FBS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

19. MRID 488252-29 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 disinfectant against Polio serotype I (PV-1), ATCC VR-1562" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 03/12/2012. Laboratory Project Number: GR 2873.

This study was conducted against Polio serotype I (PV-1), ATCC VR-1562. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The virus stock pools were prepared from the supernatant of infected MA-104 cell culture. Each PV-1 stock pool was titered and stored in an ultra-low temperature freezer. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus dried at 21.7°C and 49% relative humidity for 12 minutes. The host MA-104 cells were plated into 24-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45° angle, 4 inches away from surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. An aliquot of the 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% FBS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

20. MRID 488252-30 "AOAC 18th Edition Germicidal Spray Test on NAIC

88494-1 against Respiratory Syncytial Virus (RSV), ATCC VR-26" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/07/2011. Laboratory Project Number: GR 2882.

This study was conducted against Syncytial Virus (RSV), ATCC VR-26. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The RSV stock pools were prepared from the supernatant of infected Hep-2 cell culture. Each RSV stock pool was titered and stored in an ultra-low temperature freezer. The harvested viral stock contains 5% organic load. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus dried at 20.9°C and 55% relative humidity for 14.5 minutes. The Host MRC-5 cells were plated into 6-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45° angle, 4 inches away hard surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one(1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% FBS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

21. MRID 488252-31 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 against Human Rhinovirus, ATCC VR-340" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/20/2011. Laboratory Project Number: GR 2877.

This study was conducted against Human Rhinovirus, ATCC VR-340. Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Human Rhinovirus stock pools were prepared from the supernatant of infected Vero cell culture. Each rhinovirus stock pool was titered and stored in an ultra-low temperature freezer. The harvested viral stock contains 5% organic load. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus dried at 21.8°C and 63.4% relative humidity was 14 minutes. The host Vero cells were plated into 6-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45° angle, 4 inches away from surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one (1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of 100% FBS and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 33°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors

was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

22. MRID 488252-32 "AOAC 18th Edition Germicidal Spray Test on NAIC 88494-1 against Human Rotavirus, ATCC VR-340" for Wedge Disinfectant, by Chuan Wang, Ph.D. Study Completion Date: 12/21/2011. Laboratory Project Number: GR 2876.

This study was conducted against Human Rotavirus, Strain WA (TC Adapted). Two lots (Lot nos. P8176 and P8073) of the product, Wedge Disinfectant, were tested using the AOAC Official Methods of Analysis, 18th edition. The Human Rotavirus stock pools were prepared from the supernatant of infected MA-104 cell culture. Each virus stock pool was titered and stored in an ultra-low temperature freezer. The harvested viral stock contains 5% organic load. An aliquot of 0.2 mL of the virus was spread over a marked area of a sterilized glass Petri dish. The virus dried at 21.4°C and 49.5% relative humidity for 16.50 minutes. The MA-104 cells were plated into 24-well plates and incubated at 37°C, 5% CO_2 and 90% relative humidity. Once dried, the slides were exposed to the disinfectant product by spraying and allowing exposure for one minute. Three test sprays were done at a 45°angle, 4 inches away from surface. Afterwards, the disinfectant/challenge virus mixture was scraped off the hard surface and mixed thoroughly. Immediately after one (1) minute contact time, a 0.1 mL of disinfectant/virus reaction mixture was taken and the disinfection activity was quenched immediately by diluting (30-fold) with 2.9 mL of EX Cell MDCK Serum Free medium/L-glutamine/ PS/Trypsin 50µL and flowing through a Sephadex column. The collected eluate was designated as 10^{-2} dilution. Subsequent serial dilutions were carried out to 10^{-6} per lot. Dilutions were then inoculated into the prepared host cell plates, four determinations were made per each well. Inoculated plates were incubated at 37°C, 5% CO_2 and 90% relative humidity. Presence or absence of virus survivors was monitored for 7 days. Controls included those for cell viability, virus stock, plate recovery/column titer, cytotoxicity, and Neutralization effectiveness confirmation. Efficacy data were generated at the lower certified limits for the two active ingredients.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/Total No. Tested			Carrier Population Control CFU/carrier
		Lot No. P7980	Lot No. P8073	Lot No. P8176	
488252-10	*Staphylococcus aureus*	0/60	0/60	0/60	5.5×10^6
	Pseudomonas aeruginosa	0/60	0/60	0/60	1.7×10^6
	Salmonella enterica	0/60	0/60	0/60	2.3×10^6
488252-11	*Acinetobacter baumannii*	0/10	0/10	------	4.5×10^5
488252-12	*Burkholderia cepacia*	0/10	0/10	------	2.1×10^4

488252-13	*Campylobacter jejuni*	0/10	0/10	------	1.0×10^4
488252-14	*Escherichia coli* O157:H7	0/10	0/10	------	3.6×10^5
488252-15	*Klebsiella pneumoniae*	0/10	0/10	------	1.6×10^5
488252-16	*Listeria monocytogenes*	0/10	0/10	------	1.8×10^4
488252-17	*Staphylococcus aureus* (MRSA)	0/10	0/10	------	1.4×10^6
488252-18	*Streptococcus pyogenes*	0/10	0/10	------	1.8×10^5
488252-19	*Enterococcus faecium*	0/10	0/10	------	4.8×10^5
488252-21	*Trichophyton mentagrophytes*	0/10	0/10	------	1.1×10^4

MRID Number	**Organism**	**Lot #**	**No. Positive/No. Tested**		
			[MPB]	**[DB]**	**[7H9]**
488252-20	*Mycobacterium bovis*	P7980	0/10	0/10	0/10
		P8073	0/10	0/10	0/10
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MRID Number	**Organism**	**Results**			**Dried Virus Control ($TCID_{50}$/0.1 mL) Log_{10}**
		Dilution	**Lot #8176**	**Lot #8073**	
488252-22	Human Coronavirus	10^{-1}	Cytotoxicity	Cytotoxicity	4.7
		10^{-2} to 10^{-6}	Complete inactivation	Complete inactivation	
		($TCID_{50}$/0.1 mL)	≤1.5	≤1.5	
488252-23	Human Hepatitis B	10^{-1} to 10^{-2}	Cytotoxicity	Cytotoxicity	5.5
		10^{-3} to 10^{-7}	Complete Inactivation	Complete inactivation	
488252-24	Human Hepatitis C	10^{-1}	Cytotoxicity	Cytotoxicity	
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	4.5

488252-25	Herpes Simplex Type 1	10^{-1}	Cytotoxicity	Cytotoxicity	4.7
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-26	Human Immuno-deficiency Virus (HIV-1)	10^{-1}	Cytotoxicity	Cytotoxicity	6.3
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-27	Influenza Virus Type A2	10^{-1}	Cytotoxicity	Cytotoxicity	5.3
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-28	Norovirus Using Feline Calicivirus	10^{-1} to 10^{-2}	Cytotoxicity	Cytotoxicity	5.7
		10^{-3} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-29	Poliovirus Serotype	10^{-1}	Cytotoxicity	Cytotoxicity	4.5
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-30	Respiratory Syncytial Virus	10^{-1}	Cytotoxicity	Cytotoxicity	4.7
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-31	Human Rhinovirus	10^{-1}	Cytotoxicity	Cytotoxicity	5.5
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	
488252-32	Human Rotavirus	10^{-1}	Cytotoxicity	Cytotoxicity	4.7
		10^{-2} to 10^{-6}	Complete Inactivation	Complete Inactivation	

VI CONCLUSIONS

1. The submitted efficacy data (MRID No. 488252-10) support the use of the product, Wedge Disinfectant, as a disinfectant with bactericidal activity against *Pseudomonas aeruginosa, Staphylococcus aureus,* and *Salmonella enterica* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. One of the three product lots tested was at least 60 days old at the time of testing. Killing was observed in the subcultures of all 60 carriers tested against three lots of product. Dried carrier counts were at acceptable. Neutralization confirmation testing showed positive growth of the organisms. Purity controls reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data (MRID Nos. 488252-11 thru 488252-20) support the use of the product, Wedge Disinfectant, as a disinfectant with bactericidal activity against the following bacteria on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. Killing was observed in the subcultures of all 60 carriers tested against two lots of product. Dried carrier counts were acceptable. Neutralization confirmation testing showed positive growth of the organisms. Purity controls reported as pure. Sterility controls did not show growth.

MRID No. 48825211	*Acinetobacter baumanni*
MRID No. 48825212	*Burkholderia cepacia*
MRID No. 48825213	*Campylobacter jejuni*
MRID No. 48825214	*Escherichia coli* serotype O157:H7
MRID No. 48825215	*Klebsiella pneumoniae*
MRID No. 48825216	*Listeria monocytogenes*
MRID No. 48825217	*Staphylococcus aureus* (MRSA)
MRID No. 48825218	*Streptococcus pyogenes*
MRID No. 48825219	*Enterococcus faecium*

3. The submitted efficacy data (MRID No. 488252-20) do not support the use of the product, Wedge Disinfectant, as a disinfectant with tuberculocidal activity against *Mycobacterium bovis* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute (60 seconds). The Agency is unfamiliar with the substitution of the Dubos broth, this does not satisfy testing in Kirchner's medium.

4. The submitted efficacy data (MRID No. 488252-21) support the use of the product, Wedge Disinfectant, as a disinfectant with fungicidal activity against *Trichophyton mentagrophytes* on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute (60 seconds). All fungal spores were killed. Neutralization confirmation testing showed positive growth of the microorganism. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

5. The submitted efficacy data support the use of the product, Wedge Disinfectant, as a disinfectant with virucidal activity against the following for use on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute (60 seconds). Recoverable virus titers were achieved of at least 10^4. A log reduction of at least 3 logs was achieved beyond the cytotoxic level. A recoverable virus titer of at least 10^4 was achieved.

MRID No. 488252-22	Human Coronavirus
MRID No. 488252-23	Human Hepatitis B Virus
MRID No. 488252-24	Human Hepatitis C Virus
MRID No. 488252-25	Herpes Simplex Virus Type 1
MRID No. 488252-26	Human Immunodeficiency Virus (HIV-1)
MRID No. 488252-27	Influenza Virus Type A2
MRID No. 488252-28	Norovirus using Feline Calicivirus as surrogate
MRID No. 488252-29	Poliovirus serotype I
MRID No. 488252-30	Respiratory Syncytial Virus
MRID No. 488252-31	Human Rhinovirus
MRID No. 488252-32	Human Rotavirus

VII RECOMMENDATIONS

1. The proposed label claims that the product, Wedge Disinfectant, is effective as a disinfectant on hard, non-porous surfaces against the following microorganisms in the presence of organic soil (5% blood serum) at full strength for the contact times listed:

Microorganism	Contact Time
Pseudomonas aeruginosa	1 minute
Staphylococcus aureus	1 minute
Salmonella enterica	1 minute
Acinetobacter baumanni	1 minute
Burkholderia cepacia	1 minute
Campylobacter jejuni	1 minute
Escherichia coli serotype O157:H7	1 minute
Klebsiella pneumoniae	1 minute
Listeria monocytogenes	1 minute
Staphylococcus aureus (MRSA)	1 minute
Streptococcus pyogenes	1 minute
Enterococcus faecium	1 minute
Human Coronavirus	1 minute
Human Hepatitis B Virus	1 minute
Human Hepatitis C Virus	1 minute
Herpes Simplex Virus Type 1	1 minute
Human Immunodeficiency Virus (HIV-1)	1 minute
Influenza Virus Type A2	1 minute
Norovirus using Feline Calicivirus as surrogate	1 minute
Polio Virus Serotype 1	1 minute
Respiratory Syncytial Virus	1 minute
Human Rhinovirus	1 minute
Human Rotavirus	1 minute

These claims are acceptable as supported by efficacy data provided by the applicant. Soil load claims in excess of 5% soil are unacceptable.

2. The proposed label claims that the product, Wedge Disinfectant, is effective as a disinfectant on hard, non-porous surfaces against *Mycobacterium bovis* in the presence of organic soil (5% blood serum) at full strength at 1minute. A medium substitution rationale must be provided to the Agency.

3. The following changes are recommended to the proposed label:

- Remove statement, "Kills 99.99% of bacteria that can cause food borne illness.....in 1 minute. The disinfection tests are qualitative; therefore quantitative assessments are unacceptable.
- Remove the pesticidal claims associated with "quick". The agency has determined that contact times of ≤ 10 seconds are consistent with the term quick.
- Claims for sanitization must be removed from the label as efficacy data were not provided to support this claim.